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July 20, 2015

Via ECF
The Honorable Carol Bagley Amon, U.S.D.J.
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: *Alberto, et al. v. Colgate-Palmolive Company, et al.*
Case No. 14-CV-5649 (CBA) (CLP)

Dear Judge Amon,

I am counsel to Plaintiffs on this matter and write to supplement responses to questions posed by the Court during the oral argument held on July 15, 2015.

1. Are Defendants allowed variance if it is intentional?

By definition, variance has to be unintentional. If variance was intentional, it would simply be fraud. Fraud as to quantity is expressly prohibited by the NIST and by the states in which Plaintiffs' reside, as they have expressly adopted the NIST standards.[1] Section 15 of the NIST's Uniform Weights and Measures Law states:

> No person shall: (a) sell, offer, or expose for sale a quantity less than the quantity represented; nor (b) take more than the represented quantity when, as buyer, he/she furnishes the weight or measure by means of which the quantity is determined; nor (c) represent the quantity in any manner calculated or tending to mislead or in any way deceive another person.

NIST Handbook 130 at 28.

NIST Handbook 155[2], intended as a handbook for weights and measures administrators nationwide, states as follows:

> The delivery of full weight and measure and the elimination of fraud and misrepresentation have been objectives in commercial transactions from the time of the inception of quantity

[1] *See* NIST Handbook 130 at 10-11 *http://www.nist.gov/pml/wmd/pubs/upload/hb130-2015-final-web.pdf*
[2] http://www.nist.gov/pml/wmd/pubs/upload/hb-155-final.pdf

> determination of merchandise down to the present day. It has been demonstrated that there are always some who will avail themselves of an opportunity for an unfair or dishonest advantage, and that, even though this number be relatively small, the results of their fraudulent practices constitute a serious problem in their community. Again, it has been shown that another group, larger than the one just mentioned but still constituting only a small percentage of those engaged in business, are careless in the conduct of their affairs to such a degree that the community suffers almost as much from their unintentional errors as from the intentional inaccuracies of the fraudulently minded. Still a third group adds its share to the total of inequities attendant upon commercial quantity determination, and this is made up of those whose errors result from ignorance rather than from carelessness or intent to defraud. Of these three groups, one can be more sympathetic toward the last, the ones who know no better, than toward the other two. But it must not be overlooked that short weight or measure is equally damaging to the injured party whatever its underlying cause.

NIST Handbook 155 at 2.

The allowance of variance is proper only during the course of manufacturing, due to variations in machinery and environment that can't be controlled. Other courts have agreed with the "unintentional" requirement to allow for variance. *See Lopez v. Nissan N. Am.*, Inc., 201 Cal. App. 4th 572, 575-76 (Cal. App. Ct. 2011), where the Court of Appeals affirmed the trial court's decision, finding that "passenger vehicle odometers are 'correct' if they register actual mileage within the 4 percent tolerance ***and the designer or manufacturer does not deliberately miscalibrate them*** to underregister or overregister mileage." *Id*. at 576. Given that *Bell Atl.Corp. v. Twombly*, 550 U.S. 544 (2007) only dictates a plausibility standard, and that the Second Amended Complaint ("SAC") alleges that certain sample lines were intentionally short-weighted (SAC ¶ 37, 39, 40, 42), such claims must be allowed to proceed. The issue of intent is an issue of fact that is more properly explained during discovery and although the SAC does not list out the sampling results of all the products tested, it does list out the product lines where shortfalls were observed. At the very least, Plaintiffs' claims for intentional shortfall is plausible on its face and such claims must be allowed to proceed.

2. What is Plaintiffs' basis for the argument that the claims at issue are not preempted?

While individuals are prohibited from bringing private enforcement actions under the FDCA, that prohibition does *not* prevent individuals from bringing private actions based on state law claims, even where the remedial objectives are consistent with the FDCA. The FDCA, 21 U.S.C. §§ 301 *et seq.*, governs the sale of foods, drugs and cosmetics in the United States. The classification of a product as a food, drug, or cosmetic, affects the regulations by which the product must abide. The FDA has explained that "[s]ome products meet the definitions of both cosmetics and drugs," for example, "when a product has two intended uses" as with "deodorants that are also antiperspirants. . . [s]uch products must comply with the requirements for both cosmetics and drugs."[3] SAC ¶ 27. Defendants' products are deodorants with antiperspirant, and are subject to FDCA requirements and state laws that mirror the FDCA requirements.

Under 21 U.S.C. §§ 352(a) and 352(i)(1), respectively, "[a] drug or device shall be deemed to be misbranded. . . [i]f its labeling is false or misleading in any particular" and "[i]f it is a drug

[3] *See* http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm

and its container is so made, formed, or filled as to be misleading. . . ." SAC ¶ 24. Under 21 U.S.C. §§ 362(a) and 362(d), respectively, "[a] cosmetic shall be deemed to be misbranded. . . [i]f its labeling is false or misleading in any particular" and [i]f its container is so made, formed, or filled as to be misleading. . . ." SAC ¶ 26. The states in which Plaintiffs reside forbid the misbranding of drugs and cosmetics in language identical or similar to its federal counterparts. *See* SAC ¶ 29. Plaintiffs' state law claims are not preempted.

New York

Drug: "A drug or device shall be deemed to be misbranded: a. If its labeling is false or misleading in any particular. . . h.(1)If it is a drug and its container is so made, formed or filled as to be misleading. . . ." New York Edn. Law § 6815.

Cosmetic: "A cosmetic shall be deemed to be misbranded: a. If its labeling is false or misleading in any particular . . . d. (1) [i]f its container is so made, formed, or filled as to be misleading. . . ." New York Edn. Law § 6818.

New Jersey

Drug: "For the purposes of this subtitle a drug or device shall also be deemed to be misbranded: a. If its labeling is false or misleading in any particular . . . i. (1) If it is a drug and its container is so made, formed or filled as to be misleading . . . ." NJ Rev Stat § 24:5-18.

Cosmetic: "For the purposes of this subtitle a cosmetic shall also be deemed to be misbranded: a. If its labeling is false or misleading in any particular . . . i. (1) If it is a drug and its container is so made, formed or filled as to be misleading . . . ." NJ Rev Stat § 24:5-18.1.

California

Drug: "Any drug or device is misbranded if its labeling is false or misleading in any particular." California Health & Safety Code § 111330.

"Any drug or device is misbranded if its container is so made, formed, or filled as to be misleading." California Health & Safety Code § 111390.

Cosmetic: "Any cosmetic is misbranded if its labeling is false or misleading in any particular." California Health & Safety Code § 111730.

"Any cosmetic is misbranded if its container is so made, formed, or filled as to be misleading." California Health & Safety Code § 111750.

Plaintiffs' claims are based on violations of the misbranding laws above but also on violations of state consumer protection laws. NY GBL § 349 provides that "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are . . . unlawful." SAC ¶ 82. N.J.S.A. 56:8-2 provides that "[t]he act, use or employment by any person of any unconscionable practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of material fact with the intent that others rely upon such concealment, suppression or omission, …is declared to be an unlawful practice…" SAC ¶ 108. California's Consumers Legal Remedies Act, Cal. Civ. Code § 1770(a)(5), prohibits "[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have." SAC ¶ 123. Plaintiffs have relied on FDCA regulations merely to establish the standard of duty. *See Grove Fresh Distrib. Inc. v. The Flavor of Fresh Foods, Inc.*, 720 F. Supp. 714, 716 (N.D. Ill. 1989) ("Grove Fresh has not brought suit directly under the FDCA . . . Grove Fresh relies on the FDA regulation merely to establish the standard of duty . . . Nothing prohibits Grove Fresh from using the FDCA or its accompanying regulations in that

fashion."); *In re Bayer Corp.*, 701 F. Supp. 2d 356, 376 (E.D.N.Y. 2010) ("[P]laintiffs have threaded the needle and alleged conduct that violates the FDCA but sounds in traditional principles of state law and would give rise to recovery even had the FDCA never been enacted.").

In *Hendricks v. StarKist Co.*, 30 F. Supp. 3d 917 (N.D.C.A. 2014), where the plaintiff alleged to being misled that "StarKist's 5-ounce cans of tuna contain less tuna than would be expected", the Court held that a state-law claim relying on a standard consistent with the FDCA standard may not be preempted, as articulated in a line of Supreme Court authority. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (analyzing whether a specific provision of the FDCA preempted state law claims based upon a violation of FDA regulations enacted thereunder and finding no preemption); *Wyeth v. Levine*, 555 U.S. 555, 581 (2009) (holding that state law product defect claims based upon inadequate drug warning labels were not preempted simply because the FDA regulated, and had approved, the drug warning label for the product in question). Here, there is similarly no preemption because Plaintiffs have only alleged that Defendants should provide clarifying statements regarding net weight, they are not seeking to impose additional or different filling requirements on Defendants.

3. What is Plaintiffs' basis for the argument that a "special relationship" exists between Plaintiffs and Defendants here?

To determine the existence of a "special relationship" in a commercial transaction, a court examines three factors: "'whether the person making the representation held or appeared to hold a unique or special expertise; whether a special relationship of trust or confidence existed between the parties; and whether the speaker was aware of the use to which the information would be put and supplied it for that purpose.'" *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 474–75 (E.D.N.Y 2013) (citing and quoting *Landesbak Baden-Wurttemberg v. Goldman, Sachs & Co.*, 821 F. Supp. 2d 616, 623–24 (S.D.N.Y. 2011)); *Amos*, 2014 WL 1303133, at *5 (quoting *Suez Equity Investors, L.P. v. Toronto-Dominion Bank*, 250 F.3d 87, 103 (2d Cir. 2001)).

New York courts have assessed these factors in relation to the commercial purchase of a product. In *Hughes*, the court found that a special relationship existed where the defendant held itself out as having some special expertise and the labeling contained language suggesting scientific backing to the claims. *Hughes*, 930 F. Supp. 2d at 475. Like in *Hughes*, where the court found a plausible claim for negligent misrepresentation because the defendants "understood that the content of their labeling, packaging . . . would be used by consumers for the purpose of evaluating Ester–C," here, Plaintiffs allege a similarly plausible claim. The SAC states that Defendants, as the manufacturers, packagers, labelers and initial sellers of the Products purchased by Plaintiffs and members of the Class, are in the unique position of being able to provide accurate information about their Products." SAC ¶ 153. Moreover, Defendants had exclusive knowledge of material facts not known or reasonably accessible to the Plaintiffs. *Id*. at 155.

Respectfully submitted,

/s/ C.K. Lee